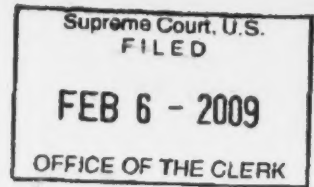


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No. 08-867

In the Supreme Court of the United States

APOTEX CORP., *et al.*,

Petitioners,

v.

ASTRAZENECA AB, *et al.*,

Respondents.

**On Petition for Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit**

BRIEF IN OPPOSITION

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TABLE OF CONTENTS

INTRODUCTION.....	1
COUNTERSTATEMENT	3
REASONS FOR DENYING THE WRIT	5
A. The Court of Appeals' Precedent is Clear and Uniform.	5
B. The Court of Appeals' Rule is Consistent With This Court's Precedent And Long-Standing Policy Determinations.	9
1. The Court of Appeals' Rule Follows Long-Standing Precedent and Policy.	9
2. <i>Scott Paper</i> Does Not Require a Contrary Result.....	10
3. Petitioners' Policy Arguments Are Also Flawed.	13
C. This Case Does Not Provide a Suitable Vehicle For Decision in Any Event Because Petitioners' Evidence Was Rejected Below.....	16
D. The Second Question Presented in the Petition Turns Solely on Fact-Bound Determinations Involving No Important Legal Issue.	17
CONCLUSION	21

RULE 29.6 STATEMENT

Pursuant to Rule 29.6, Respondents state that the parent corporations or publicly held companies holding 10% or more of the stock of AstraZeneca AB, Aktiebolaget Hassle or AstraZeneca LP are AstraZeneca PLC and Zeneca Wilmington, Inc. and that the parent corporation or publicly held company holding 10% or more of the stock of KBI-E, Inc. and KBI, Inc. is Merck & Co., Inc.

TABLE OF AUTHORITIES

CASES

<i>American Hoist & Derrick Co. v. Sowa & Sons,</i> 725 F.2d 1350 (Fed. Cir. 1984).....	14, 15
<i>Astra Aktiebolag v. Andrx Pharm., Inc.,</i> 222 F.Supp.2d 423 (S.D.N.Y. 2002).....	19
<i>Avia Group Int'l, Inc. v. L.A. Gear Calif, Inc.,</i> 853 F.2d 1557 (Fed. Cir. 1988).....	15
<i>Baxter Healthcare Corp. v. Spectramed, Inc.,</i> 49 F.3d 1575 (Fed. Cir. 1995).....	5, 6
<i>Beckson Marine, Inc. v. NFM, Inc.,</i> 292 F.3d 718 (Fed. Cir. 2002).....	10
<i>Belcher v. Stengel,</i> 429 U.S. 118 (1976).....	17
<i>Blonder-Tongue Labs., Inc. v. Univ. of Illinois Foundation,</i> 402 U.S. 313 (1971).....	10
<i>Board of License Comm'rs of Town of Tiverton v. Pastore,</i> 469 U.S. 238 (1985).....	17
<i>Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.,</i> 246 F.3d 1368 (Fed. Cir. 2001).....	10
<i>Brown v. 3M,</i> 265 F.3d 1349 (Fed. Cir. 2001).....	10

<i>California v. San Pablo & Tulare R. Co.</i> , 149 U.S. 308 (1893)	17
<i>Cardinal Chem. Co. v. Morton Int'l, Inc.</i> , 508 U.S. 83 (1993)	14
<i>Dow Chem. Co. v. Astro-Valour, Inc.</i> , 267 F.3d 1334 (Fed. Cir. 2001)	10
<i>Fiskars, Inc. v. Hunt Mfg. Co.</i> , 221 F.3d 1318 (Fed. Cir. 2000)	7, 8
<i>Harris Corp. v. IXYS Corp.</i> , 114 F.3d 1149 (Fed. Cir. 1997)	7
<i>In re Omeprazole Patent Litig.</i> , 84 Fed.Appx. 76 (Fed. Cir. 2003)	19
<i>Jones v. Hildebrandt</i> , 432 U.S. 183 (1977)	17
<i>Kim v. ConAgra Foods, Inc.</i> , 465 F.3d 1312 (Fed. Cir. 2006)	6
<i>Lear Siegler, Inc. v. Aeroquip Corp.</i> , 733 F.2d 881 (Fed. Cir. 1984)	15
<i>Lewmar Marine, Inc. v. Barient, Inc.</i> , 827 F.2d 744 (Fed. Cir. 1987)	10
<i>Lisle Corp. v. AJ Mfg. Co.</i> , 398 F.3d 1306 (Fed. Cir. 2005)	10
<i>Markman v. Westview Instruments, Inc.</i> , 517 U.S. 370 (1996)	1, 6, 7, 11

<i>Mycogen Plant Science, Inc. v. Monsanto Co.</i> , 243 F.3d 1316 (Fed. Cir. 2001).....	10
<i>Nazomi Comms., Inc. v. ARM Holdings, Plc.</i> , 403 F.3d 1364 (Fed. Cir. 2005).....	7
<i>O'Reilly v. Morse</i> , 56 U.S. 62 (1853)	18
<i>Peters v. Active Mfg. Co.</i> , 129 U.S. 530 (1889)	1, 9, 10, 12
<i>Polaroid Corp. v. Eastman Kodak Co.</i> , 789 F.2d 1556 (Fed. Cir. 1986).....	10
<i>Pope Manufacturing Co. v. Gormully</i> , 144 U.S. 224 (1892)	9
<i>Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.</i> , 324 U.S. 806 (1945)	9
<i>Rhine v. Casio, Inc.</i> , 183 F.3d 1342 (Fed. Cir. 1999).....	7
<i>Scott Paper Co. v. Marcalus Mfg. Co.</i> , 326 U.S. 249 (1945)	passim
<i>Sinclair & Carroll Co. v. Interchemical Corp.</i> , 325 U.S. 327 (1945)	14
<i>SmithKline Beecham Corp. v. Apotex Corp.</i> , 439 F.3d 1312 (Fed. Cir. 2006).....	6
<i>Tate Access Floors, Inc. v. Interface Architectural Res., Inc.</i> , 279 F.3d 1357 (Fed. Cir. 2002).....	5, 6, 7, 13

<i>The Monrosa v. Carbon Black Export, Inc.,</i> 359 U.S. 180 (1959)	17
<i>Warner-Jenkinson Co., Inc. v. Hilton-Davis Chem. Co.,</i> 520 U.S. 17 (1997)	7
<i>Westinghouse Co. v. Formica Co.,</i> 266 U.S. 342 (1924)	11
STATUTES	
35 U.S.C. §282	10, 14
RULES	
Sup. Ct. R. 10	20

INTRODUCTION

This case is not appropriate for review on either of the questions presented. On the first question, the petition fails to meet the criteria for review for at least three reasons:

First, the Court of Appeals has consistently applied a methodical and rigorous comparison of the patent claim against the prior art (to determine validity) and the accused product (to determine infringement). Where the evidence indeed shows that the accused product and the prior art are the same, and the patent claims read on the prior art, then the patent is invalid. In such a case, the accused infringer has a complete defense to the action for infringement. The Court of Appeals' precedent traces back more than a century to the rule that: "[t]hat which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (1889). The decision below follows this long line of precedent, which necessarily and logically rejects the short-hand "practicing the prior art" defense in favor of a claim-based analysis of patent infringement and validity, an approach required not only by *Peters*, but also by this Court's more recent precedent in *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

Second, Petitioners' assertion that the Court of Appeals' rejection of a "practicing the prior art" defense is out of step with this Court's precedent is wrong. Petitioners' reliance on *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945) is misplaced. The Court's statement there that "[t]he assignor has a complete defense to an action for infringement where the alleged infringing device is that of an expired patent," *id.* at 258 (emphasis added), is no way inconsistent with the Court of Appeals' approach because invalidation of a patent is just as "complete" a defense to an action for infringement as is a judgment of non-infringement. *Scott Paper* additionally does not bear the weight placed upon it by

Petitioners because it was a narrow decision addressing the breadth of the doctrine of assignor estoppel. The case did not purport to establish the broad rule that Petitioners now seek to attribute to it.

Third, even if there were cause to consider the first question presented, this case is an exceptionally poor vehicle for doing so. The trial record is devoid of any evidence that would support Petitioners' "practicing the prior art" defense. Thus, the outcome of this case can not be determined by the Court's answer to the first question. The district court expressly rejected Petitioners' proffered scientific evidence purportedly demonstrating the structure of Petitioners' accused product and the prior art as not based on proper, representative samples. (Pet. App. at 264a-265a). The Court of Appeals did not disturb these fact-bound determinations on appeal. (Pet. App. at 32a-35a). The question presented is therefore moot in the context of this case.

Perhaps this last point explains why Petitioners did not see fit to raise the issue in their petition for rehearing or rehearing *en banc* at the Court of Appeals. Petitioners' ambivalence, coupled with the unanimity of the Court of Appeals in a long line of decisions on this point, demonstrates further why the question presented is not appropriate for this Court's review.

As to the second question presented by Petitioners—*i.e.*, whether Petitioners' product suffered from a chemical reaction that the patented invention was designed to prevent—*certiorari* should be denied because this fact-bound question was decided on the specific evidence in this case and affirmed by the Court of Appeals. It presents no legal question of general significance.

COUNTERSTATEMENT

Respondents' claims of infringement of its '505 and '230 patents against Petitioners (Apotex) and other defendants (Mylan/Esteve, Lek and Impax) were heard in a bench trial over 42 days of extensive testimony by scientific experts and fact witnesses. The district court's opinion comprises hundreds of pages of detailed analysis of the scientific evidence. (Pet. App. at 45a-401a).

The trial court conducted a thorough claim construction analysis, taking into account the prior art as well as the other relevant evidence in accordance with well-established practice. (Pet. App. at 110a-126a). The trial court then carefully compared each element of the asserted patent claims against the structure of Petitioners' product, and determined that Petitioners' product literally infringed a number of asserted claims. (Pet App. 108a-126a; 244a-280a). The court similarly analyzed each of the other defendants' accused products, finding some to infringe and some not to infringe, depending on whether or not they met all of the claim elements. (Pet App. at 131a-244a; 280a-312a).

The trial court further engaged in a detailed analysis of the validity of the two patents. The court compared each prior art reference asserted as anticipatory by Petitioners and the other defendants against the patent claims, and also engaged in a detailed review of the prior art asserted to make the patent claims obvious. (Pat App. at 338a-400a). The court concluded that the defendants had not shown by clear and convincing evidence that any of Respondents' asserted patent claims was invalid. (Pet. App. at 400a).

Petitioners did not raise a "practicing the prior art" defense as a legal theory separate and apart from the

conventional literal infringement and invalidity theories adjudicated by the trial court, and the trial court did not decide any such question. However, Petitioners did attempt to adduce evidence, through the testimony of their experts Dr. Signorino and Dr. Cima, consisting of test samples made specifically for the litigation. Petitioners proffered these samples to show the characteristics of Petitioners' accused product as well as of a product allegedly made according to one of the prior art references (the EP '495 patent). The trial court rejected both pieces of evidence. As to the samples allegedly showing Petitioners' product, the court found: "This evidence is of little value, however, because Apotex did not demonstrate that Dr. Signorino's Reproduction Pellets were representative of Apotex's product." (Pet App. at 264a). As to the samples allegedly showing the prior art product, the court found: "Furthermore, Plaintiffs presented evidence that Dr. Signorino did not follow the teachings of the '495 Patent, but instead modified certain ingredients and procedures in creating his reproductions." (Pet. App. at 265a). The Court of Appeals did not disturb either fact-bound determination. (Pet. App. at 32a-35a).

In its brief on appeal, Petitioners did make mention of their contention that their accused product "practiced the prior art," albeit each time without citation to specific evidence in the record. However, Petitioners in urging reversal dedicated the vast majority of their briefing to the traditional argument that their product did not infringe because it did not meet all of the elements of the patent claims as properly construed. Insofar as the Court of Appeals considered the Petitioners to have raised "practicing the prior art" as a separate legal theory for reversal, the court stated in two sentences:

Apotex also argues that its manufacturing process merely practices the prior art, citing European

Patent Application No. EP 124,495 A2 ("the '495 European application"). It is well established, however, that "practicing the prior art" is not a defense to infringement. *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365-69 (Fed. Cir. 2002); *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995). (Pet. App. at 32a).

This is the entire extent of the Court of Appeals' pronouncement on the "practicing the prior art" issue.

Petitioners did not raise a "practicing the prior art" argument in their petition for rehearing or rehearing *en banc* before the Court of Appeals. The question is squarely presented, only for the first time now, in the current petition for *certiorari*.

REASONS FOR DENYING THE WRIT

The Court of Appeals' precedent is uniform and consistent, and comports completely with this Court's precedent and the broad policy goals of the Patent Statute. No confusion or lack of clarity exists as to the legal and evidentiary requirements for a showing of patent infringement. Because the petition points to no important, unsettled legal issue, *certiorari* should be denied.

A. The Court of Appeals' Precedent is Clear and Uniform.

The Court of Appeals has consistently resisted calls by litigants to create the same short-hand "practicing the prior art" defense to literal patent infringement urged by Petitioners here. The Court of Appeals' precedent is clear and consistent and soundly grounded in precedent and policy.

The court first addressed the issue expressly in *Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1583 (Fed. Cir. 1995). In rejecting a “practicing the prior art” defense, the Court of Appeals explained that “[l]iteral infringement exists if each of the limitations of the asserted claim(s) read on, that is, are found in the accused device. Questions of obviousness in light of the prior art go to validity of the claims, not to whether the accused device infringes.”

In *Tate Access Floors, Inc. v. Interface Arch. Res., Inc.*, 279 F.3d 1357, 1365-69 (Fed. Cir. 2002); the court elaborated on its *Baxter* decision and the rubric for determining patent infringement under a “literal infringement” theory—which is ordinarily the primary theory on which infringement is determined in patent actions. First, the claims of the patent are construed and then the claims, as construed, are compared to the accused device. *Id.* at 1366. This is precisely the long-standing approach that this Court re-affirmed most recently in *Markman*, 517 U.S. at 374 (“Victory in an infringement suit requires a finding that the patent claim covers the alleged infringer’s product or process, which in turn necessitates a determination of what the words in the claim mean.”) (internal quotations omitted). Indeed, claim construction is the first step in the determination of both infringement and validity and the Court of Appeals has been careful to warn that the same claim construction must be used for both purposes. *See, e.g., Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1324 (Fed. Cir. 2006) (“The same claim construction governs for validity determinations as for infringement determinations.”); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1316 (Fed. Cir. 2006) (“claims must be construed the same way for validity and for infringement”).

Evidence of the prior art is sometimes useful in the claim construction analysis because where the claim language is ambiguous, the court should generally adopt a more narrow construction that preserves the validity of the claim over the prior art. *Id.* at 1367; *see, e.g., Harris Corp. v. IXYS Corp.*, 114 F.3d 1149, 1153 (Fed. Cir. 1997) (“claims should be read in a way that avoids ensnaring the prior art if it is possible to do so”). However, where no genuine ambiguity exists, and the claim language clearly reads on the prior art, the claim is invalid. *Id.* at 1367; *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999) (“if the only claim construction that is consistent with the claim’s language and the written description renders the claim invalid, then the axiom [that claims should be construed ‘if possible’ to sustain their validity] does not apply and the claim is simply invalid”); *Nazomi Comms., Inc. v. ARM Holdings, Plc.*, 403 F.3d 1364, 1368 (Fed. Cir. 2005) (same). As the Court of Appeals summarized it in *Tate Access*: “Fairness and the public notice function of the patent law require the courts to afford patentees the full breadth of clear claim language, and bind them to it as well.” 279 F.3d at 1367; *Cf. Markman*, 517 U.S. at 390 (describing the importance to the public of “certainty” and “uniformity” in the construction of patent claims).

Contrary to what is stated in the petition (Pet. at 14-15), the Court of Appeals did not deviate from this approach in *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318 (Fed. Cir. 2000). *Fiskars*—like the precedent on which it relied—was an infringement case decided under the doctrine of equivalents, rather than under a literal infringement theory. *See Warner-Jenkinson Co., Inc. v. Hilton-Davis Chem. Co.*, 520 U.S. 17 (1997) (explaining nature and application of the patent law doctrine of equivalents). The Court of Appeals in *Tate Access* explained why *Fiskars* is inapposite in a literal infringement case:

With respect to literal infringement, these cases [including *Fiskars*] are inapposite. The doctrine of equivalents expands the reach of claims *beyond* their literal language. That this expansion is guided and constrained by the prior art is no surprise, for the doctrine of equivalents is an equitable doctrine and it would not be equitable to allow a patentee to claim a scope of equivalents encompassing material that had been previously disclosed by someone else, or that would have been obvious in light of others' earlier disclosures. But this limit on the equitable extension of literal language provides no warrant for constricting literal language when it is clearly claimed.

279 F.3d at 1367 (emphasis in original).

The case at bar was decided under a literal infringement theory and not under the doctrine of equivalents. Thus, Petitioners' claim that the Court of Appeals in the case at bar has "repudiated" a defense it had previously "affirmed" in *Fiskars* is simply incorrect. (Pet at 15). The Court of Appeals has never endorsed a "practicing the prior art" defense in a literal infringement case. Rather, the court requires a methodical analysis in which the claims are first construed and then compared separately to the accused device (to determine infringement) and the prior art (to determine validity). That was the approach employed by the lower courts in this case.

B. The Court of Appeals' Rule is Consistent With This Court's Precedent And Long-Standing Policy Determinations.

1. The Court of Appeals' Rule Follows Long-Standing Precedent and Policy.

The Court of Appeals' approach has roots that go back at least to the 1889 *Peters* decision, a case ignored in the petition. In *Peters*, the Court endorsed the view that:

Had the complainant's invention been first in time and patented, the Binghamton sheath would have been an infringement; and, conversely, had the Binghamton sheath been patented, the complainant's would have been an infringement. That which infringes, if later, would anticipate, if earlier.

Peters, 129 U.S. at 537. It has thus long been clear that where there is unity among what is patented (*i.e.*, the invention defined by the patent claims as properly construed), the accused infringing device and the prior art, the result is that the patent is invalid. This result well serves long-standing policies that encourage elimination of patents that block the use of public domain technology. See, *e.g.*, *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly ...") (internal quotations omitted); *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945) ("A patent by its very nature is affected with a public interest. ... [It] is an exception to the general rule against monopolies and to the right to access to a free and open market."); *Blonder-Tongue Labs., Inc. v. Univ.*

of *Illinois Foundation*, 402 U.S. 313, 342-346 (1971) (examining the detrimental impact on the public from multiple patent infringement suits if the patentee is allowed to re-litigate validity of a patent once declared invalid).¹

The Court of Appeals has consistently recognized the applicability of the *Peters* rule in cases of asserted similarities between the accused device and a prior art device, but in each case has applied a rigorous and methodical analysis in which the patent claims are first construed and then compared separately to both the accused infringement and the prior art. See, e.g., *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1573 (Fed. Cir. 1986); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987); *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 1324 (Fed. Cir. 2001); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001); *Brown v. 3M*, 265 F.3d 1349, 1352-53 (Fed. Cir. 2001); *Dow Chem. Co. v. Astro-Valour, Inc.*, 267 F.3d 1334, 1339-40 (Fed. Cir. 2001); *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 726 (Fed. Cir. 2002); *Lisle Corp. v. AJ Mfg. Co.*, 398 F.3d 1306, 1315 (Fed. Cir. 2005). These cases, in addition to those mentioned *ante*, uniformly recognize the principle that if the patent claims cover the prior art, they are invalid because one cannot claim patent protection for what was already in the prior art.

2. *Scott Paper* Does Not Require a Contrary Result.

Petitioners' argue that this Court's 1945 decision in *Scott Paper* requires that the Court now establish a new defense to literal patent infringement separate and apart from the

¹ Of course, a challenge to patent validity must be undertaken and decided in light of the statutory presumption of validity in 35 U.S.C. §282, as discussed *infra*.

traditional claim-based analysis. As mentioned, that traditional analysis, which requires construction of the patent claims as its first step, was most recently sanctioned in *Markman* in 1996, a case that dealt extensively with the proper methodology for construing patent claims.

In *Scott Paper*, the patentee acquired by assignment a patent from the respondent and later asserted that the respondent infringed the patent. The respondent defended on the ground that its machine was a copy of what was described in a different, expired, prior art patent. 326 U.S. at 251. The narrow question presented was whether the assignor of the patent (the respondent) was "estopped by virtue of his assignment to defend a suit for infringement of the assigned patent on the ground that the alleged infringing device is that of a prior art, expired patent." *Id.* at 250. The reference to estoppel was a reference to the rule established in *Westinghouse Co. v. Formica Co.*, 266 U.S. 342, 349 (1924) that "an assignor of a patent rent is estopped to attack the utility, novelty or validity of a patented invention which he has assigned or granted as against any one claiming the right under his assignment or grant. As to the rest of the world, the patent may have no efficacy and create no right of monopoly; but the assignor can not be heard to question the right of his assignee to exclude him from its use." (internal citations omitted).

The Court held in *Scott Paper* that the doctrine of assignor estoppel established in *Westinghouse* did not apply "so as to penalize the use of the invention of an expired patent." 326 U.S. at 254. The Court concluded that "the patent laws preclude the patentee of an expired patent and all others including petitioner from recapturing any part of the former patent monopoly; for those laws dedicate to all the public the ideas and inventions embodied in an expired patent." *Id.* at 256. The Court went on: "It follows that the

patent laws preclude the petitioner assignee from invoking the doctrine of estoppel, as a means of continuing as against respondent, his assignor, the benefit of an expired monopoly, and they preclude the assignor from estopping himself from enjoying rights which it is the policy of the patent laws to free from all restrictions." *Id.*

It is clear from the Court's reasoning that it viewed the patent laws as preventing one from validly patenting subject matter that had been dedicated to the public in an expired prior art patent, and that this rule trumped the assignor estoppel doctrine. This holding is in no way inconsistent with the Court of Appeals decision below. The result of such an attempt to claim prior art subject matter—under *Peters*, *Scott Paper* or the Court of Appeals' precedent—is that the patent claim, if it is indeed correctly construed to encompass prior art, is invalid. In this way, "[t]he assignor has a complete defense to *an action* for infringement where the alleged infringing device is that of an expired patent." *Id.* at 258 (emphasis added).

Petitioners place heavy reliance on this last quotation (*see* Pet. at 3, 13) and attempt to interpret the words as if the Court had made a refinement to how a court must evaluate a theory of infringement. This ignores the emphasized words "*an action* for infringement." Read in context, it is clear from this sentence that the Court was simply speaking of the end result of the *action*, *i.e.*, that the patentee cannot prevail. Logically, of course, it is just as much a "complete defense to an action for infringement" if the patent claims are invalid than if the claims are not infringed. The rest of the opinion, as explained above, makes clear that the reason the patentee does not prevail is that his patent, if claiming prior art, is invalid.

The Court of Appeals was presented with the same argument based on *Scott Paper* in *Tate Access* and came to the same conclusion. 279 F.3d at 1368-69. There, the Court of Appeals recognized that "the *Scott Paper* rationale was based on the premise that the assigned patent would be invalid due to anticipation were it coextensive with the expired prior art patent." *Id.* at 1369. The Court of Appeals went on to note that "[t]he statement [in *Scott Paper*] that, in such circumstances, the assignor has a 'complete defense to an *action for infringement*' must be understood in context." *Id.* (emphasis in original). It is telling that the court went on to analyze infringement and validity the traditional way, by construing the claims and comparing them to the accused infringing device and the prior art. *Id.* at 1370-72. The lower courts did no differently in the case at bar.

3. Petitioners' Policy Arguments Are Also Flawed.

Petitioners' argument for the creation of a new patent law "practicing the prior art" defense is thus ungrounded in precedent. Petitioners' policy-based arguments are equally baseless. Petitioners urge that creating such a defense would make it "unnecessary" for an accused infringer to prove invalidity of the patent. According to Petitioners, this would make for a more "balanced and fair" process in which the accused infringer can avoid having to carry its burden of proof of invalidity by clear and convincing evidence, despite the contrary requirement of the Patent Statute and precedent, and also allow the patent owner to avoid an invalidity challenge. (Pet. at 18-23). Petitioners' argument suffers from a number of flaws.²

² Petitioners even go so far as to state that "[t]he Federal Circuit has effectively eliminated an accused infringer's ability to prove non-infringement of a valid patent." (Pet. at 19). This is clearly

As discussed above, important policy considerations dictate that the validity of patent rights should be adjudicated, when called into question. See pp. 9-10, *ante*. Indeed, this Court has stated that “‘of the two questions [validity and infringement], validity has the greater public importance.’” *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 100 (1993) (quoting *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330 (1945)) and has “emphasized the importance to the public at large of resolving questions of patent validity.” *Id.* However, in making this determination, the Patent Statute requires that:

“A patent shall be presumed valid. Each claim of a patent ... shall be presumed valid independently of the validity of other claims The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such validity.

35 U.S.C. §282. The Court of Appeals has explained that the presumption arises in part due to the deference owed to patent examiners, who are employees of an administrative agency (the U.S. Patent & Trademark Office) presumed to have some expertise in the pertinent art and presumed to have properly done their job in examining the patent. *American Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359 (Fed. Cir. 1984).

The court has further explained that the presumption operates only as a “procedural device” that “places on a party asserting invalidity the initial burden of going forward to

wrong, as indicated by the plethora of Court of Appeals’ decisions cited *ante*, all of which carefully evaluate validity and infringement separately according to established norms under which the patent claims are first construed and then compared separately to the accused and prior art devices.

establish a *prima facie* case" and "establishes that the burden of persuasion on the issue of invalidity also rests throughout the litigation on the party asserting invalidity." *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 885 (Fed. Cir. 1984). "The presumption is one of law, not fact, and does not constitute 'evidence' to be weighed against a challenger's evidence." *Avia Group Int'l, Inc. v. L.A. Gear Calif., Inc.*, 853 F.2d 1557, 1562 (Fed. Cir. 1988). "In the end, the question is whether *all* of the evidence establishes that the validity challenger so carried his burden as to have persuaded the decisionmaker that the patent can no longer be accepted as valid." *Lear Siegler*, 733 F.2d at 885 (emphasis in original). As the Court of Appeals summarized it in *American Hoist*:

To summarize on this point, §282 creates a presumption that a patent is valid and imposes the burden of proving invalidity on the attacker. That burden is constant and never changes and is to convince the court of invalidity by clear evidence. Deference is due the Patent and Trademark Office decision to issue the patent with respect to evidence bearing on validity which it considered but no such deference is due with respect to evidence it did not consider. All evidence bearing on the validity issue, whether considered by the PTO or not, is to be taken into account by the tribunal in which validity is attacked.

725 F.2d at 1360.

Petitioners offer no cogent argument for deviating from established law and policy under which questions regarding a patent's validity should not be avoided, but adjudication of validity should occur against the backdrop of the statutory presumption of validity. Nothing is "unfair" or "unbalanced"

in requiring the courts and litigants to be mindful of the procedural burdens imposed by the Patent Statute in the course of adjudicating patent validity. But this procedural device creates no difficulties that would justify a wholesale abandonment of the Court of Appeals' approach in favor of a short-hand "practicing the prior art" defense. That approach would, contrary to this Court's precedent, avoid important determinations of patent validity in cases where an accused infringer asserts that the patentee is claiming prior art subject matter that should be free for public use.

C. This Case Does Not Provide a Suitable Vehicle For Decision in Any Event Because Petitioners' Evidence Was Rejected Below.

Even if it were inclined to announce a new "practicing the prior art" defense to infringement, the Court should not do so in this case because a decision favorable to Petitioners on that legal question cannot affect the outcome. The record is devoid of any evidence, accepted by the courts below, that would demonstrate that Petitioners actually were practicing a process, or manufacturing a product, identical to the prior art. It is telling that Petitioners never attempt to cite any finding by the lower courts that would support their legal contention, and indeed, no such finding exists.

In fact, the district court flatly rejected the Petitioners' proffered evidence purportedly showing the physical characteristics of its accused product and a product allegedly made according to the prior art. Specifically, the district court found that test samples allegedly showing Petitioners' product had "little value" because Petitioners did not demonstrate that the samples were representative of Petitioners' product. (Pet App. at 264a). The district court also found that test samples allegedly representing the prior art did not actually follow the teachings of the prior art. (Pet.

App. at 265a). The Court of Appeals did not disturb either fact-bound determination. (Pet. App. at 32a-35a).

"The court is not empowered to decide moot questions or abstract propositions, or to declare ... principles or rules of law which cannot affect the result as to the thing in issue in the case before it." *California v. San Pablo & Tulare R. Co.*, 149 U.S. 308, 314 (1893). Where it is apparent from the factual record that a decision on the question presented could not affect concrete rights of the litigants before the Court, the Court has routinely declined to exercise its *certiorari* jurisdiction. See, e.g., *Board of License Comm'rs of Town of Tiverton v. Pastore*, 469 U.S. 238, 239-40 (1985); *Jones v. Hildebrandt*, 432 U.S. 183, 187 (1977); *Belcher v. Stengel*, 429 U.S. 118, 119-20 (1976); *The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 183-84 (1959).

Given the state of this record, even were the Court to grant the petition and announce a new defense to patent infringement based on "practicing the prior art" as Petitioners have requested, it could not possibly benefit Petitioners, whose evidence on this point has already been found fatally deficient. No ruling by this Court could remedy this defect. The Court should not therefore use this case as a vehicle to take up the moot question as to whether to create a new defense to patent infringement.

**D. The Second Question Presented in the Petition
Turns Solely on Fact-Bound Determinations
Involving No Important Legal Issue.**

Petitioners' second question—"whether an accused infringer can be liable if the invention involves a feature designed to prevent a naturally occurring chemical reaction when the accused product contains that feature only as a result of the natural chemical reaction the invention is

designed to prevent"—is so highly dependent on the specific facts of a given case as to present no important legal question of general consequence. Resolution of the issue in a given case would require factual findings as to the intended purpose of the invention, the scope of the patent disclosure, and the physical and chemical processes occurring in connection with the accused product, among other fact-bound questions. To those facts as found, a court would have to apply the legal construction of the claims of the particular patent-in-suit to determine infringement and validity. It is not apparent how any legal rule of general application could be fashioned that would both advance the patent system and lead to a just result in all cases.

The legal application of construed patent claims to facts involving the patented invention and accused product by the lower courts in the case *sub judice* is in no way inconsistent with the holding of *O'Reilly v. Morse*, 56 U.S. 62 (1853), the authority on which Petitioners rely. In *O'Reilly*, the Court rejected as invalid the attempt to claim "the use of the motive power of the electric or galvanic current, which I call electromagnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances" because to sustain such a claim would foreclose all possible improvements in telecommunications technology and thus the claim was deemed "too broad, and not warranted by law." *Id.* at 113. However, the Court allowed the patentee to validly claim his invention in more concrete terms in seven other claims. *Id.* at 85-86, 112. As is readily apparent in this case, Respondent's claims are to a concrete and specific pharmaceutical product having certain coating layers and specific ingredients. These claims are not so broadly drawn that it can plausibly be argued that they encompass a law of nature or natural phenomenon. (See Pet. App. at 4a-5a (quoting claims of '505 and '230 patents)). No inconsistency

therefore exists between this case and the precedent on which Petitioners rely.

Petitioners' real quarrel is with the district court's construction of the specific claim element "inert subcoating ... disposed on said core region" which the district court identified as the issue on which Petitioners' infringement depended. (Pet. App. at 250a). In making this determination, the district court adopted its previous construction of this claim element (which appears in both the '505 and '230 patents) that did not require that the inert subcoating be formed in any particular manner. (Pet. App. at 251a). The district court had first made this claim construction during litigation involving the First Wave defendants. *Astra Aktiebolag v. Andrx Pharm., Inc.*, 222 F.Supp.2d 423, 464, 468-75 (S.D.N.Y. 2002). The Court of Appeals had affirmed. *In re Omeprazole Patent Litig.*, 84 Fed.Appx. 76 (Fed. Cir. 2003). After construing this claim element, the district court conducted a detailed review of the scientific evidence to determine whether Petitioners' accused product contained an inert subcoating and whether such a coating met the claim element. (Pet. App. at 251a-275a).

Whether or not a discrepancy exists between what Petitioners allege was the "purpose" of the invention as stated in the written description of the patents-in-suit and the district court's construction of the "inert subcoating" claim element was fully explored at the Court of Appeals. That court explained:

We rejected that argument in the appeal from the district court's first wave trial based on our conclusion that the phrase "[d]isposed on" does not specify any method or structure involved in application of the subcoating." 84 Fed. Appx. 76,

80 (Fed. Cir. 2003). We reject that argument in this appeal for the same reason.

(Pet App. at 31a).

Put simply, both the district court and the Court of Appeals have construed the specific patent claims at issue in this case in light of all the relevant evidence and concluded that the factual question as to how the subcoating is formed is legally irrelevant to the question of whether the claim element is met for purposes of infringement. Whether or not the accused product contains a naturally occurring subcoating, as urged by Petitioners, is not germane to the infringement of these two particular patents.

The issue raised in the second question is thus inextricably intertwined with the particular claim language and disclosure of the '505 and '230 patents-in-suit in this case. The Court of Appeals' decision establishes no general rule of law that would govern the interpretation or application of patent claims in any other case not involving these patents. The court's decision in no way establishes any rule of law that allows patenting of "a law of nature or a natural phenomenon" as alleged in the petition. (Pet. at 11). The Court of Appeals, like the district court, did nothing more than analyze the written description and claim language of these two patents and reached the conclusion that the claim language does not limit the invention to the method by which the subcoating is formed.

Rule 10 states: "A petition for a writ of *certiorari* is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." Sup. Ct. R. 10. Petitioners' second question presents nothing more than an assertion that the claim construction reached by the district court and the Court of

Appeals was wrong, as was the application of that claim construction to the particular products in issue in this case. This is not the type of question that the rules contemplate as suitable for review on *certiorari*.

CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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